DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 22, 2015

Meditech Spine, LLC
Mr. Jason Gromek
Director of Engineering
1447 Peachtree Street, Northeast, Suite 440
Atlanta, Georgia 30309

Re: K142345
Trade/Device Name: Talos®-C (HA) Cervical Intervertebral Body Fusion Devices
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: January 20, 2015
Received: January 22, 2015

Dear Mr. Gromek:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

meditech spine, llc.
1447 Peachtree St NE Suite 440, Atlanta GA 30309 | p (678) 974-5287 | f (404) 759-2104 | support@meditechspine.com

Indications for Use Form

510(k) Number (if known): K142345

Device Name: Talos®-C (HA) Cervical Intervertebral Body Fusion Devices

Indications for Use:

Talos®-C (HA) Cervical Intervertebral Body Fusion Devices are intervertebral body devices intended for use in skeletally mature patients with Degenerative Disc Disease (DDD) of the cervical spine at one level from C2-T1. Cervical degenerative disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on the posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by history and radiographic studies. Talos®-C (HA) Cervical IBF Devices are intended to be used with autologous bone graft to facilitate fusion.

Non-operative treatment prior to treatment with Talos®-C (HA) Cervical Intervertebral Body Fusion Devices is six (6) weeks.

Talos®-C (HA) Cervical IBF Devices are to be implanted via an open anterior approach. Talos®-C (HA) Cervical IBF Devices are also to be used with supplemental fixation.

Prescription Use ☒ 21CFR 801, Subpart D **OR** Over-the-Counter Use ☐ 21CFR 801.109

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

meditech spine, llc.

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510(k) Summary

As required by section 807.92(c)

Meditech Spine, LLC is requesting marketing clearance for the Talos®-C (HA) Cervical Intervertebral Body Fusion Devices. Summary prepared on the 18th of February, 2015.

A. Sponsor/Manufacturer: Meditech Spine, LLC
Registration Number: 3009405289
Jason Gromek, Director of Engineering
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678-974-5287 Phone
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B. Trade Name: Talos®-C (HA) Cervical Intervertebral Body Fusion Devices
Common Name: Spinal Implant
Classification Name: Intervertebral body fusion device (21 CFR 888.3080 Class II, Product Code ODP)

C. Predicate Device: K 122850: Meditech Advisors, LLC Talos®-C Cervical Intervertebral Body Fusion Devices

D. Device Description:
The Talos®-C (HA) Cervical Intervertebral Body Devices (Talos®-C (HA) Cervical IBF Devices) are made of the polymer, hydroxyapatite impregnated polyetheretherketone (HA PEEK). The devices are open devices with ridged teeth on superior and inferior ends to resist implant pullout. The Talos®-C (HA) Cervical IBF Devices are rectangular devices and have curved lateral walls and rounded edges. The implants are available in a range of sizes as well as flat and lordotic angled implants to accommodate variations in patient's anatomy. In addition, tantalum markers at the opposite ends are offered which allows the Talos®-C (HA) Cervical IBF Device radiological confirmation for proper positioning.

E. Intended Use:
Talos®-C (HA) Cervical Intervertebral Body Fusion Devices are intervertebral body devices intended for use in skeletally mature patients with Degenerative Disc Disease (DDD) of the cervical spine at one level from C2-T1. Cervical degenerative disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on the posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by history and radiographic studies. Talos®-C (HA) Cervical IBF Devices are intended to be used with autologous bone graft to facilitate fusion.

Non-operative treatment prior to treatment with Talos®-C (HA) Cervical Intervertebral Body Fusion Devices is six (6) weeks.

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Talos®-C (HA) Cervical IBF Devices are to be implanted via an open anterior approach. Talos®-C (HA) Cervical IBF Devices are also to be used with supplemental fixation.

F. Technological Characteristics:
The technological characteristics of the Talos®-C (HA) Cervical IBF Devices are the same as the predicate device, except for the material. The new material is hydroxyapatite filled polyetheretherketone (HA PEEK). HA is a naturally occurring mineral in bone and is widely used in the orthopedic field.

G. Non-clinical Testing:
Tests according to ASTM 2077 and ASTM 2267 were performed on the Talos®-C (HA) Cervical IBF Devices to establish equivalency to the predicate device. The tests include static compression, compression shear and torsion tests, dynamic compression, compression shear and torsion tests, as well as subsidence testing. Simulated aging was performed on Talos®-C (HA) IBF Devices, which then were subjected to additional dynamic compression and torsion tests in accordance with ASTM 2077. The Talos®-C (HA) is equal in mechanical function and properties to the predicate device, establishing equivalency in safety and effectiveness.

H. Conclusion:
The testing completed as well as a comparison of the technological characteristics have demonstrated that the Talos®-C (HA) Cervical IBF Devices are substantially equivalent to the predicate device.